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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,941	10/25/2005	Dirk Wybe Grijpma	5100-000015/US	9691

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EXAMINER	
MCCLENDON, SANZA L	
ART UNIT	**PAPER NUMBER**
1711	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,941	GRIJPMA ET AL.	
	Examiner	Art Unit	
	Sanza L. McClendon	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Ana Paula Pêgo et al** (*Polymer, Volume 44, Issue 21, October 2003, Pages 6495-6504*).

Pêgo et al sets forth enhanced mechanical properties of 1,3-trimethylene carbonate polymers and networks useful in biomedical devices such as support matrices and scaffolds. Pêgo et al sets forth enhancing the mechanical properties of polymeric TMC by irradiating molded articles using gamma radiation dosages of up to 40 kGy in an inert atmosphere, such as N_2. The number average molecular weight of the polymeric TMC used for irradiation treatment of greater than 200,000. Pêgo et al sets forth creep stresses of less than about 10% of the yield stress, a swelling degree of

less than 400%, and a gel fraction of greater than 10% by weight for the irradiated polymeric TMC moldings.

Pêgo et al does not expressly teach sterilization of the medical devices obtained from the process, however one of ordinary skill in the art would have found it obvious to sterilize a medical device that is used for human contact. The motivation would have been a reasonable expectation of obtaining a device safe for in vivo/in vitro practices in the absence of evidence to the contrary and/or unexpected results.

4. Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ritter et al (4, 496,446).

Ritter et al teaches irradiating structural surgical elements, such as an anastanosis ring device, with gamma radiation to improve properties such as initial strength, in vivo strength and degradation loss rate of said strength properties. Said surgical elements are made of bioabsorbable polymers, such as polyglycolides and copolymers of glycolides with trimethylene carbonate-column 10, line 48. Ritter et al discloses the use of gamma radiation dosages of up to 10 Mrad (100 kGy). In addition, Ritter et al teaching ethylene oxide sterilization of said structural surgical devices-see column 4, lines 35 to 40. Regarding the properties as found in claims 12-14, Ritter et al discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al. In the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

5. Claims 1-4, 8-9, 11, 15-21, and 23-24 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang et al (7,037,983 and 2003/0232929).

Huang et al teaches methods of making functional biodegradable polymers. Said modifications are obtained by polymerizing a vinyl monomer with a biodegradable polymer in the presence of an initiator system, such as a photoinitiator with a light source. Said biodegradable polymers include synthetic polymers such as copolymers of TMC, i.e., poly (glycolic acid-co-trimethylene carbonate) copolymer. Said irradiation sources include UV and other high ionizing radiation and other energy irradiation sources. Therefore, it is deemed that the irradiation sources found in claim 8 are envisioned within the reference. The biodegradable polymers of Huang et al are disclosed as useful for biodegradable materials for usage in biomedical a applications.

Huang et al does not expressly teach the number average molecular weight of the polymers with TMC, however since applicant has not established the criticality of the molecular weights as instantly claimed it is deemed that any molecular weight homopolymers/copolymer would have worked equally as well in the absence of evidence to the contrary and/or unexpected results.

6. Claims 1-4, 8-14, 15-21 and 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roby et al (5,889,075).

Roby et al sets forth irradiated surgical sutures and methods of making them. Said surgical sutures are fabricated from a copolymer of dioxanone, trimethylene carbonate, and glycolide, which is treated with gamma irradiation to enhance the properties. Said copolymers can be arranged in sequences as found in columns 2, lines 59-68 to column 3, lines 1-14. The irradiation treatment is from a total dose rate from about 2 to about 12 Mrad in an inert atmosphere while under vacuum. Thus the examiner deems claims 10 and 11 are envisioned in the reference. Regarding the properties as found in claims 12-14, Roby et al discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al. In the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 3-9, 18, 21, and 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Amsden et al (2003/010524 and 6,984,393).

Amsden et al discloses photo- and thermally crosslinked biodegradable/biocompatible elastomeric polymers. Said crosslinked polymers

can be useful in biomedical devices, such as scaffolds. Said polymers are elastomeric star polymers that have been combined with monomers and photoinitiators that are irradiated to produce said crosslinked polymers. Said radiation can be ultraviolet radiation. Said star polymer can be caprolactone/lactide copolymers and said crosslinking monomer can be a carbonate such as trimethylene carbonate. Said crosslinked polymers are disclosed as being made into scaffolds for implantation, wherein Amsden et al teaches sterilizing them prior to implantation. This appears to anticipate the instantly claimed invention as written, therefore it is deemed the properties found in instant claims 12-14 are inherent to the Amsden et al polymers. Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

9. Claims 1, 3-8, 12-14, 16-18, and 23-24 are rejected under 35 U.S.C. 102(b and/or e) as being anticipated by Pathak (2003/0077272; 2002/0114775; 7,211,651; 7,057,019; and 6,887,974).

Pathak sets forth polymeric crosslinking agents having an inert water-soluble component, a biodegradable component, and a functional component having reactive functional groups reactive with functional groups on proteins or other biological agents. Said polymeric crosslinking agents can be used to prepare hydrogels in applications, such as wound dressings. Said crosslinking takes place via irradiation with an ionizing radiation source. Per figure 5, Pathak sets forth the use of TMC as an example of the biodegradable component. Pathak sets forth photo-irradiating polymeric crosslinking agents comprising TMC therefore said polymeric crosslinking agents should inherently have the properties as outlined in claims 12-14.

Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed

product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L. McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sanza L. McClendon
Examiner
Art Unit 1711

SMc